SEP 1 2 2000

K002517

3.0 Summary of Safety and Effectiveness Information

SPONSOR:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME:

USS VAS

CLASSIFICATION:

The classification of the Synthes USS VAS components is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3070: Pedicle Screw Spinal System. The product code is MNI, KWP, KWQ and MNH. The Panel code is 87.

PREDICATE DEVICE:

Synthes Spine Click'X - K992739

DEVICE DESCRIPTION:

The USS VAS components consists of new side-opening pre-assembled pedicle screws (which includes a pedicle screw, side-opening rod/screw connection and locking ring combination), and sleeve. The side-opening pre-assembled pedicle screw is affixed to the spine using previously cleared rods (straight or curved), nut and Low Profile Transconnector components which are part of the currently cleared Click'X System – K992739. In addition, when used with 6.0/6.0 mm parallel connectors of the USS, the Synthes USS VAS can be linked to the USS.

INTENDED USE:

Posterior Components
When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes USS is intended for treatment of severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral

spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system, the Synthes USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The Click'X **and USS VAS** components of the Synthes USS, when used as a posterior pedicle screw fixation system, are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal tumor and failed previous fusion (pseudoarthrosis).

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In addition, when used with 3.5/6.0 mm parallel connectors, the Synthes USS can be linked to the CerviFix System.

Anterior Components
The Anterior Components of the USS are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

MATERIAL: The components are made from titanium alloy TiAlNb (ASTM F1295).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2000

Mr. Jonathan Gilbert
Senior Regulatory Affairs Manager
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K002517
Trade Name: USS VAS
Regulatory Class: II
Product Code: KWP, KWQ, MNH, MNI
Dated: August 11, 2000
Received: August 15, 2000

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer -

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K002517

Device Name: USS VAS

Indications:

Posterior Components

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Indications for Use Statement (continued)

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER ~~PAGE IF~~ NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

Anne R. Hochmuth
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002517